

AMENDMENT

Please enter the following amendments. Deleted subject matter is indicated with strikethrough text and added subject matter is indicated with underlined text. The current listing of Claims supersedes all previous versions.

In the Claims

1. (Currently amended) An implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric carrier region that comprises said therapeutic agent and which releases said therapeutic agent upon administration to a patient, said polymeric carrier region comprising a silicone block copolymer comprising a plurality of siloxane units and a plurality of non-siloxane units, said block copolymer comprising (i) a block of said siloxane units selected from a polydimethylsiloxane block, a polydiethylsiloxane block, a polymethylethylsiloxane block and a polymethylphenylsiloxane block and (ii) a block of elevated T_g non-siloxane units, wherein the ~~device further comprises a barrier region disposed over the carrier region~~ polymeric release region is in the form of a coating layer that covers all or a part of said medical device.

2-4. (Canceled)

5. (Original) The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is selected from a catheter, a guide wire, a balloon, a filter, a stent, a stent graft, a vascular graft, a vascular patch and a shunt.

6. (Original) The implantable or insertable medical device of claim 1, wherein said implantable or insertable medical device is adapted for implantation or insertion into the coronary vasculature, peripheral vascular system, esophagus, trachea, colon, biliary tract, urinary tract, prostate or brain.

7. (Original) The implantable or insertable medical device of claim 1, wherein said therapeutic agent is selected from one or more of the group consisting of anti-thrombotic agents,

anti-proliferative agents, anti-inflammatory agents, anti-migratory agents, agents affecting extracellular matrix production and organization, antineoplastic agents, anti-mitotic agents, anesthetic agents, anti-coagulants, vascular cell growth promoters, vascular cell growth inhibitors, cholesterol-lowering agents, vasodilating agents, and agents that interfere with endogenous vasoactive mechanisms.

8. (Original) The implantable or insertable medical device of claim 1, wherein said silicone copolymer has an elongation at break of at least 25% at ambient temperature.

9. (Currently amended) The implantable or insertable medical device of claim 1, wherein said ~~non-siloxane units~~ are elevated T_g non-siloxane units ~~corresponding to monomers~~ are selected from vinyl monomers, aromatic monomers, methacrylic monomers, acrylic monomers and alkene monomers.

10. (Canceled)

11. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block of said elevated T_g non-siloxane units is selected from poly(vinyl monomer) blocks, poly(aromatic monomer) blocks, poly(methacrylic monomer) blocks, poly(acrylic monomer) blocks and poly(alkene monomer) blocks.

12. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block of said elevated T_g non-siloxane units is selected from substituted and unsubstituted polystyrene blocks.

13. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block of said elevated T_g non-siloxane units is selected from substituted and unsubstituted poly(alkyl methacrylate) blocks.

14. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block of said elevated T_g non-siloxane units is selected from poly(styrene) blocks,

poly(methyl methacrylate) blocks, poly(ethyl methacrylate) blocks, poly(isopropyl methacrylate) blocks, poly(isobutyl methacrylate) blocks, poly(t-butyl methacrylate) blocks and poly(cyclohexyl methacrylate) blocks.

15. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said ~~block copolymer comprises (a) a first glass transition temperature that is greater than ambient temperature~~ block of said elevated T_g non-siloxane units comprise monomers selected from unsubstituted vinyl aromatics, vinyl substituted aromatics, ring-substituted vinyl aromatics, vinyl monomers, aromatic monomers, methacrylic monomers, acrylic monomers and alkene based monomers and ~~(b) a second glass transition temperature that is less than ambient temperature.~~

16. (Currently amended) The implantable or insertable medical device of claim 15, wherein said ~~first glass transition temperature~~ elevated T_g non-siloxane units have a T_g that is greater than 75 °C and said ~~second glass transition temperature that is~~ siloxane units have a T_g less than 0°C.

17. (Canceled)

18. (Currently amended) The implantable or insertable medical device of claim 1, wherein said polymeric release region further comprises a supplemental polymer selected from

- a) polycarboxylic acid polymers and copolymers;
- b) acetal polymers and copolymers;
- c) acrylate and methacrylate polymers and copolymers;
- d) cellulosic polymers and copolymers;
- e) polyoxymethylene polymers and copolymers;
- f) polyimide polymers and copolymers;
- g) polysulfone polymers and copolymers;
- h) polyamide polymers and copolymers;
- i) resins selected from alkyd resins, phenolic resins, urea resins, melamine resins, epoxy resins, allyl resins and epoxide resins;

- j) polycarbonates;
- k) polyacrylonitriles;
- l) polyvinylpyrrolidones;
- m) polymers and copolymers of vinyl monomers and which are selected from polyvinyl alcohols, polyvinyl halides, ethylene-vinylacetate copolymers (EVA), polyvinylidene chlorides, polyvinyl ethers, polystyrenes, styrene-maleic anhydride copolymers, styrene-butadiene copolymers, styrene-ethylene-butylene copolymers, acrylonitrile-styrene copolymers, acrylonitrile-butadiene-styrene copolymers, styrene-butadiene copolymers and styrene-isobutylene copolymers, polyvinyl ketones, polyvinylcarbazoles, and polyvinyl esters;
- n) polybenzimidazoles;
- o) ionomers;
- p) polyalkyl oxide polymers and copolymers;
- q) glycosaminoglycans;
- r) polyesters selected from polyethylene terephthalates and aliphatic polyesters;
- s) polyether polymers and copolymers selected from polyarylethers, polyether ketones, and polyether ether ketones;
- t) polyphenylene sulfides;
- u) polyisocyanates;
- v) polyolefin polymers and copolymers selected from polypropylenes, polyethylenes (low and high density, low and high molecular weight), polybutylenes, poly-4-methyl-pen-1-enes, ethylene-alpha-olefin copolymers, ethylene-methyl methacrylate copolymers and ethylene-vinyl acetate copolymers;
- w) fluorinated polymers and copolymers selected from polytetrafluoroethylenes (PTFE), poly(tetrafluoroethylene-co-hexafluoropropene) (FEP), modified ethylene-tetrafluoroethylene copolymers (ETFE), and polyvinylidene fluorides (PVDF);
- x) silicone polymers and copolymers;
- y) polyurethanes;
- z) p-xylylene polymers;
- aa) polyiminocarbonates;
- bb) copoly(ether-esters) selected from polyethylene oxide-polylactic acid copolymers;
- cc) polyphosphazines;

- dd) polyalkylene oxalates;
- ee) polyoxaamides and polyoxaesters;
- ff) polyorthoesters;
- gg) biopolymers selected from polypeptides, proteins, polysaccharides and fatty acids and esters thereof; and
- hh) blends and copolymers of the foregoing.

19. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block copolymer comprises at least two different types of said elevated T_g non-siloxane units.

20. (Original) The implantable or insertable medical device of claim 1, wherein said medical device is sterilized using a quantity of radiation effective to kill pathogens.

21. (Canceled)

22. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block of said siloxane units corresponds to a rubbery phase within said release region at ambient temperatures, and wherein said block of said elevated T_g non-siloxane units corresponds to a hard phase within said release layer at ambient temperatures.

23. (Currently amended) The implantable or insertable medical device of ~~claim 10~~ claim 1, wherein said block copolymer is selected from a diblock copolymer, a triblock copolymer and a graft copolymer.

24-27. (Canceled)

Please add New Claims 28 – 31:

28. (New) The implantable or insertable medical device of claim 1, comprising a plurality of said blocks of elevated T_g non-siloxane units as endblocks or as side chains.
29. (New) The implantable or insertable medical device of claim 28, wherein said blocks of elevated T_g non-siloxane units are selected from blocks of polystyrene or poly(alkyl methacrylate).
30. (New) The implantable or insertable medical device of claim 29, wherein said copolymer is a triblock copolymer having said block of said siloxane units as a midblock and polystyrene endblocks.
31. (New) The implantable or insertable medical device of claim 1, wherein said copolymer is a graft copolymer having said block of said siloxane units as a main chain and polystyrene side chains.
32. (New) The implantable or insertable medical device of claim 1, wherein the device further comprises a barrier region disposed over the carrier region.